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APPLICATION NO.		FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.		
10/609,012	10/609,012 06/27/2003		Theo T. Nikiforov	100/07933	8342		
21569	7590	01/10/2006		EXAM	EXAMINER		
CALIPER 605 FAIRC		CIENCES, INC.	STRZELECKA, TERESA E				
		, CA 94043-2234	ART UNIT	PAPER NUMBER			
,				1637			
			DATE MAILED: 01/10/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

		Applica	tion No.	Applicant(s)					
Office Action Summary			012	NIKIFOROV, TH	EO T.				
			er	Art Unit					
		Teresa	E. Strzelecka	1637					
Period fo	The MAILING DATE of this communi or Reply	ication appears on t	he cover sheet w	vith the correspondence a	ddress				
WHIC - Exte after - If NC - Failu Any	ORTENED STATUTORY PERIOD FO CHEVER IS LONGER, FROM THE M nsions of time may be available under the provisions SIX (6) MONTHS from the mailing date of this comm o period for reply is specified above, the maximum sta- ture to reply within the set or extended period for reply- reply received by the Office later than three months a ed patent term adjustment. See 37 CFR 1.704(b).	AILING DATE OF 7 of 37 CFR 1.136(a). In no cunication. In tutory period will apply and will, by statute, cause the a	THIS COMMUNI event, however, may a will expire SIX (6) MO pplication to become A	ICATION. reply be timely filed NTHS from the mailing date of this BANDONED (35 U.S.C. § 133).	•				
Status									
1)	Responsive to communication(s) file	d on .			•				
2a)□	•	2b)⊠ This action is	non-final.						
3)□	Since this application is in condition	·		tters, prosecution as to th	ne merits is				
,—	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.								
Disposit	ion of Claims								
4)⊠	Claim(s) 1-22 is/are pending in the a	pplication.							
,	4a) Of the above claim(s) is/are withdrawn from consideration.								
5)	Claim(s) is/are allowed.								
6)🖂	Claim(s) 1-22 is/are rejected.								
7)	Claim(s) is/are objected to.								
8)[
Applicat	ion Papers								
9)🖂	The specification is objected to by the	e Examiner.							
10)🛛	The drawing(s) filed on 27 June 2003	is/are: a)⊠ accep	oted or b)□ obje	ected to by the Examiner	•				
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).								
	Replacement drawing sheet(s) including	the correction is requ	uired if the drawing	g(s) is objected to. See 37 C	OFR 1.121(d).				
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.									
Priority (ınder 35 U.S.C. § 119								
	12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No								
	3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).								
* (t received					
	See the attached detailed Office action	n for a list of the ce	runea copies no	rreceivea.					
Attachmen	t(s)								
1) Notic	e of References Cited (PTO-892)			Summary (PTO-413)					
	e of Draftsperson's Patent Drawing Review (P mation Disclosure Statement(s) (PTO-1449 or			(s)/Mail Date Informal Patent Application (PT	ГО-152)				
	r No(s)/Mail Date 10/6/03:10/10/03:1/7/05	· •	6) 🔲 Other:	·					

Application/Control Number: 10/609,012 Page 2

Art Unit: 1637

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on October 6, 2003 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

- 2. The information disclosure statement (IDS) submitted on October 10, 2003 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner with the exception of references AG, AH, AR and AS. The references AG and AH were considered but will not be printed as they are duplicates of references BI and BJ from the IDS filed October 6, 2003. The references AR and AS were not considered for two reasons. First, these are not printed publications. Then the documents are heavily redacted, and information which may be considered material to the patentability of the current claims has been deleted.
- 3. The information disclosure statement (IDS) submitted on January 7, 2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. The references were considered but will not be printed, as they are duplicates of references AO and AP from the IDS filed October 10, 2003.

Specification

4. The disclosure is objected to because of the following informalities: the first paragraph does not contain updated information concerning status of priority applications.

Appropriate correction is required.

Application/Control Number: 10/609,012 Page 3

Art Unit: 1637

Requirement for Information

An issue of public use or on sale activity has been raised in this application. In order for the examiner to properly consider patentability of the claimed invention under 35 U.S.C. 102(b), additional information regarding this issue is required as follows: in the IDS filed October 10, 2003 Applicant submitted a redacted copy of "Molecular Devices Opposition to Motion for Preliminary Injunction" and declarations of Andrew R. Barron and J. Richard Sportsman, both also heavily redacted. These documents contain references to previously existing kinase kits, which do not use antibodies (page 15 of the Opposition, second paragraph). The paragraphs which discuss the relationship of patented claims of the '141 and '774 patents (which are parents of the instant application) to prior art have been mostly deleted (paragraphs D and E), or entirely deleted (paragraphs F and G). Further, parts of the Sportsman declaration which refer to previously available kinase kits have been deleted (page 8). Therefore, Applicant is asked to furnish the missing information so that the relationship of prior art to Applicant's invention can be properly evaluated.

Applicant is reminded that failure to fully reply to this requirement for information will result in a holding of abandonment.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 7. Claims 1-10 and 11-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Mallia (U.S. Patent No. 5,527,688; cited in the IDS), as evidenced by Hawley's Condensed Chemical

Art Unit: 1637

Dictionary (page 236, 237, 12th Edition, Van Nostrand Reinhold, New York, 1993) and Whatman Product Guide (pages 65, 66, 1995).

Claims 1 and 12 will be considered together, since claim 1 is a species of claim 12.

Regarding claims 1 and 12, Mallia teaches a fluorescently labeled peptide substrates for protein kinases, i.e., they are capable of being phosphorylated (col. 2, lines 11-21; col. 3, lines 13-16 and 26-47; col. 6, lines 17-31) and a ferric ion paper having Fe³⁺ cations bound to it, where the cations bind the paper to the phosphorylated product (col. 2, lines 21-27; col. 3, lines 18-26; col. 5, lines 43-66; col. 6, lines 1-14). Mallia do not specifically teach a cationic polymer, however, as evidenced by Hawley's Condensed Chemical Dictionary, paper is made from cellulose which is a polymer of glucose (page 236). The Whatman Product Guide (page 66) teaches that the 3MM paper is made from pure cellulose, therefore, since Mallia teaches Whatman 3 MM paper modified with iminodiacetic acid (col. 5, lines 56-61) to which Fe³⁺ cations are bound, they inherently teach a polymer having multivalent cations associated with it. Mallia teaches kits (col. 4, lines 1-18).

Regarding claims 2, 3, 10, 13 and 14, Mallia teaches Fe³⁺ cations (col. 2, lines 21-27; col. 3, lines 18-26; col. 5, lines 43-66; col. 6, lines 1-14).

Regarding claims 4 and 15, Mallia teaches kemptide which a substrate for protein kinase A (col. 5, lines 26-33; col. 6, lines 18, 19), where kemptide has an amino acid sequence of LRRASLG, therefore by teaching kemptide Mallia inherently teaches a serine substrate.

Regarding claims 5 and 17, Mallia teaches Fe³⁺ cations chelated to the paper (col. 2, line 23).

Regarding claims 6 and 18, Mallia teaches Whatman 3MM paper (col. 2, lines 21-27; col. 3, lines 18-26; col. 5, lines 43-66; col. 6, lines 1-14). The Whatman Product Guide (page 66) teaches that the 3MM paper is made from pure cellulose. As evidenced by Hawley's Condensed Chemical

Application/Control Number: 10/609,012 Page 5

Art Unit: 1637

Dictionary, paper is made from cellulose which is a polymer of glucose (page 236), with molecular weight from 160 to 560 kD, anticipating the range of 5-1000 kD.

Regarding claims 7 and 19, Mallia teaches kinases C and A and tyrosine kinases (col. 1, lines 56, 57; col. 3, lines 13-17).

Regarding claims 8 and 20, Mallia teaches ATP (col. 4, lines 17, 18).

Regarding claims 9 and 21, Mallia teaches buffer solutions (col. 4, lines 9-16).

Regarding claim 16, Mallia teaches Whatman 3MM paper (col. 2, lines 21-27; col. 3, lines 18-26; col. 5, lines 43-66; col. 6, lines 1-14). The Whatman Product Guide (page 66) teaches that the 3MM paper is made from pure cellulose. As evidenced by Hawley's Condensed Chemical Dictionary, paper is made from cellulose which is a polymer of glucose (page 236), therefore by teaching Whatman 3MM paper Mallia inherently teaches a polymer.

Claim Rejections - 35 USC § 103

- 8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 9. Claims 11 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mallia (U.S. Patent No. 5,527,688; cited in the IDS), as evidenced by Hawley's Condensed Chemical Dictionary (page 236, 237, 12th Edition, Van Nostrand Reinhold, New York, 1993) and Whatman Product Guide (pages 65, 66, 1995), and Strulovici (U. S. patent No. 5,759,787).
- A) Mallia teaches performing the kinases assays in centrifuge tubes, but do not teach multiwell plates.

Application/Control Number: 10/609,012

Art Unit: 1637

B) Strulovici teaches assays for measuring kinase activity in solution using chemiluminescence and microtiter plates (col. 2, lines 66, 67; col. 3, lines 1-10), as well as phosphocellulose capture on microtiter plates (col. 6, lines 64-67).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have used the microtiter plates of Strulovici in the kinases assays of Mallia. The motivation to do so, provided by Strulovici, would have been that using microtiter plates allowed automation and high-throughput screening (col. 3, lines 8-10), and processing by a computerized robotic system (col. 5, lines 24-42).

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-6, 8, 10, 12-19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26-31 of U.S. Patent No. 6,689,565.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the

reference claims. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 26 of the '565 patent is a species of claims 1, 7, 12, 16 and 19 of the instant application. Specifically, claim 26 of the '565 patent is drawn to a kit comprising a phosphorylatable compound that comprises a fluorescent label, a kinase enzyme and a polymer having multivalent metal cations associated therewith, wherein the metal cations bind the polymer to the phosphorylated fluorescent product, therefore it contains an additional limitation of protein kinase, resulting in claim 26 being a species of claims 1, 7, 12, 16 and 1, therefore anticipating these claims.

Claim 27 of the '565 patent anticipates claims 2 and 13 of the instant application, claim 28 of the '565 patent anticipates claims 3, 10 and 14 of the instant application, claim 29 of the '565 patent anticipates claims 4 and 15 of the instant application, claim 30 of the '565 patent anticipates claims 5 and 17 of the instant application, and claim 31 of the '565 patent anticipates claims 6 and 18 of the instant application.

12. No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E. Strzelecka whose telephone number is (571) 272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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